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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,510	12/05/2003	Kazuhisa Fukushima	032094	7859

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/727,510	Applicant(s) FUKUSHIMA ET AL.	
	Examiner Jeanine A. Goldberg	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/5/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed January 3, 2006. Currently, claims 1-5 are pending. Claims 6 has been cancelled.

Election/Restrictions

2. Applicant's election without traverse of Group 1, Claims 1-5 in the paper filed January 3, 2006 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Priority

3. This application claims priority to Japanese Appln No. 2002-353559, filed December 5, 2002.

It is noted that a translation of the foreign document has not been received.

Drawings

4. The drawings are acceptable.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-5 are indefinite because the claims do not recite the basic steps of the claimed invention in a positive, active fashion (see Ex parte Erlich 3 USPQ2d, 1011). The claims describe a method characterized by a process, but the claims fail to recite any actual steps that define the method. Claim 1 further recites "the substrate side" which lacks proper antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-2, 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al. (US 6,429,027, August 6, 2002).

Chee teaches composite arrays using microspheres and methods for decoding microsphere array sensors. Chee teaches a method of decoding an array composition comprising providing an array composition and adding a plurality of decoding binding ligands to the composite array composition to identify the location of at least a plurality

of the bioactive agents (col. 3-4, lines 65-3). Chee teaches a coding/decoding system is required to identify the bioactive agent at each location in the array (col. 5, lines 30-35). The decoding systems makes use of a decoding binding ligand (DBL), generally directly labeled, that binds to either the bioactive agent or to identifier binding ligands (IBLs) attached to the beads and/or positional decoding (col. 5, lines 35-40). Chee teaches the binding should be sufficient to remain bound under the conditions of the decoding step, including wash steps (col. 15, lines 5-10). The DBLs include proteins particularly including antibodies or fragments. Antigen-antibody pairs are useful (col. 15, lines 20-25). Chee teaches using different IBLs to encode each bioactive agent (col. 16, lines 35-40). The identification of the location of the individual beads is done using one or more decoding steps comprising a binding between the labeled DBL and either the IBL or the bioactive agent (col. 19, lines 45-50). Chee teaches a spatial or positional coding system may be used where each subarray is an "area code" that can have the same tags of other subsarrays, that are separated by virtue of the location of the subarray (col. 21, lines 60-65).

Chee teaches that a key components of the invention is the use of a substrate/bead pairing that allows the association or attachment of the beads at discrete sites on the surface of the substrate such that the beads do not move during the course of the assay (col. 9, lines 40-45).

Chee teaches that the beads or microspheres may be plastics, ceramics, glass, polystyrene, methylstyrene, paramagnetic materials, for example (col. 9, lines 24-26)(limitations of Claim 4).

Chee teaches the target sequence may be a portion of a gene, a regulatory sequence, genomic DNA, cDNA, RNA (col. 13, lines 20-30)(limitations of Claim 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. (US 6,429,027, August 6, 2002) in view of Collier et al. (US Pat. 5,985,548, November 1999).

Chee teaches composite arrays using microspheres and methods for decoding microsphere array sensors. Chee teaches a method of decoding an array composition

comprising providing an array composition and adding a plurality of decoding binding ligands to the composite array composition to identify the location of at least a plurality of the bioactive agents (col. 3-4, lines 65-3). Chee teaches a coding/decoding system is required to identify the bioactive agent at each location in the array (col. 5, lines 30-35). The decoding systems makes use of a decoding binding ligand (DBL), generally directly labeled, that binds to either the bioactive agent or to identifier binding ligands (IBLs) attached to the beads and/or positional decoding (col. 5, lines 35-40). Chee teaches the binding should be sufficient to remain bound under the conditions of the decoding step, including wash steps (col. 15, lines 5-10). The DBLs include proteins particularly including antibodies or fragments. Antigen-antibody pairs are useful (col. 15, lines 20-25). Chee teaches using different IBLs to encode each bioactive agent (col. 16, lines 35-40). The identification of the location of the individual beads is done using one or more decoding steps comprising a binding between the labeled DBL and either the IBL or the bioactive agent (col. 19, lines 45-50). Chee teaches a spatial or positional coding system may be used where each subarray is an "area code" that can have the same tags of other subarrays, that are separated by virtue of the location of the subarray (col. 21, lines 60-65). Chee teaches that a key components of the invention is the use of a substrate/bead pairing that allows the association or attachment of the beads at discrete sites on the surface of the substrate such that the beads do not move during the course of the assay (col. 9, lines 40-45). Chee teaches that the beads or microspheres may be plastics, ceramics, glass, polystyrene, methylstyrene, paramagnetic materials, for example (col. 9, lines 24-26)(limitations of Claim 4). Chee

teaches the target sequence may be a portion of a gene, a regulatory sequence, genomic DNA, cDNA, RNA (col. 13, lines 20-30)(limitations of Claim 5).

Chee does not specifically teach a method of stirring beads.

However, Collier teaches beads and test mixtures are agitated to assure contact with the bead supports (see Example 2).

Therefore, it would have been prima facie obvious to the ordinary artisan at the time the invention was made to have added an agitation or stirring step to the bead method of Chee for the expected benefits taught by Collier. Collier specifically teaches the ordinary artisan would be motivated to agitate bead and test mixtures to assure contact with the bead supports. Thus, in order to ensure contact of the beads and mixtures, the ordinary artisan would have included an agitation step.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application

No. 10/960,849. Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentable distinct from each other because Claims 1-5 of the instant application is generic to all that is recited in Claims 1-4 of U.S. Patent Application No. 10/960,849. That is, Claim 1-4 of Application No. 10/960,849 falls entirely within the scope of Claims 1-5, or in other words, Claims 1-5 are anticipated by Claim 1-4 of Application No. 10/960,849. Here, claim 1-4 of U.S. Patent Application No. 10/960,849 recites a method a method for detecting a biopolymer by trapping a target biopolymer to the substrate side, which comprises the steps of: a) adding a fluorescent labeled target biopolymer and a bead, wherein a probe biopolymer and an address linker that specifies the ID of the bead are immobilized on the surface of the bead in solution (the address linker could be on antibody, peptide, or other biopolymer; b) hybridizing the target biopolymer with the probe biopolymer', and c) trapping the address linker through antigen-antibody

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interactions by using an address probe peptide, biopolymer, or antibody which is immobilized on a substrate and which is in an antigen-antibody relationship with the address linker. The instant claims are generic to all that is claimed in the '849 application.

Conclusion

9. No claims allowable over the art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.



Jeanine Goldberg

Primary Examiner

March 13, 2006